IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TRIS PHARMA,INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.	)	
	)	
	)	
Defendants.	)	

COMPLAINT

1. Tris Pharma, Inc. ("Tris" or "Plaintiff"), for its Complaint against Par Pharmaceutical, Inc. ("Par Inc.") and Par Pharmaceutical Companies, Inc. ("Par Co.") (collectively "Par" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

2. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code.

3. On information and belief, Defendants have been and are engaging in activities directed toward infringement of United States Patent No. 8,062,667 ("the '667 patent"), United States Patent No. 8,287,903 ("the '903 patent"), United States Patent No. 8,465,765 ("the '765 patent"), United States Patent No. 8,563,033 ("the '033 patent"), and United States Patent No. 8,778,390 ("the '390 patent"), by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 206926 seeking FDA approval to manufacture and commercially market their proposed product called "Methylphenidate hydrochloride 5mg/ml for extended release oral suspension" (hereinafter referred to as "Par's ANDA Product") containing the active ingredient methylphenidate HCl.

4. In a letter dated December 11, 2014, entitled "Methylphenidate Hydrochloride 5mg/ml for extended release oral suspension United States Patent Nos. 8,062,667; 8,287,903; 8,465,765; 8,563,033 and 8,778,390 Notification of Paragraph IV Certification" (hereinafter referred to as the "December 11 Letter"), Par Inc. notified Tris that it had submitted ANDA No. 206926, but that the ANDA had not yet been accepted for filing by FDA. Par also notified Tris that it intends to manufacture and commercially market Par's ANDA Product (a generic version of Quillivant XR®) before expiration of the '667, '903, '765, '033, and '390 patents.

5. Par's December 11 Letter was premature and invalid under FDA regulations. Par's December 11 Letter did not trigger Tris's statutory right to sue for infringement or commence the 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3).

6. In a letter dated December 22, 2014, entitled "Methylphenidate Hydrochloride 5mg/ml for extended release oral suspension United States Patent Nos. 8,062,667; 8,287,903; 8,465,765; 8,563,033 and 8,778,390 Notification of Paragraph IV Certification" (hereinafter referred to as the "December 22 Notice Letter"), Par Inc. notified Tris that it had filed ANDA No. 206926 and that it intends to manufacture and commercially market Par's ANDA Product (a generic version of Quillivant XR®) before expiration of the '667, '903, '765, '033, and '390 patents.

THE PARTIES

7. Plaintiff Tris is a company organized and existing under the laws of the State of New Jersey, having its principal place of business at 2033 Route 130, Suite D, Monmouth Junction, NJ 08852.

8. Tris is engaged in the business of research, development, manufacture, and sale of pharmaceutical products for sale throughout the U.S.

9. On information and belief, defendant Par Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Ram Ridge Road, Spring Valley NY 10977. On information and belief, Par Inc. is a wholly-owned subsidiary of Par Co.

10. On information and belief, Par Inc. is in the business of manufacturing, marketing, importing, distributing, preparing, and selling generic pharmaceutical products in the State of Delaware and throughout the United States.

11. On information and belief, defendant Par Co. is a corporation organized under the laws of the State of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

12. On information and belief, Par Co. is in the business of manufacturing, marketing, importing, distributing, preparing, and selling generic pharmaceutical products in the State of Delaware and throughout the United States.

13. On information and belief, Par Co. operates through and directs the actions of its wholly-owned subsidiary, Par Inc. to develop, manufacture, market, sell and distribute generic pharmaceutical products in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, and venue is proper pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

15. This Court has personal jurisdiction over Par Inc. by virtue of, *inter alia*: (1) its presence in Delaware, including its incorporation in Delaware; (2) its course of conduct that is designed to cause the sale of its products in Delaware; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

16. This Court has personal jurisdiction over Par Co. by virtue of, *inter alia*: (1) its presence in Delaware, including its incorporation in Delaware; (2) its course of conduct that is designed to cause the sale of its products in Delaware; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

17. Defendants have previously submitted to the jurisdiction of the United States District Court for the District of Delaware, and filed suit and asserted counterclaims in this Court at least in *Horizon Pharma, Inc. v. Par Pharm. Cos., Inc.*, No. 13-102, D.I. 8 (D.Del. Feb. 8, 2013); *Pronova Biopharma Norge AS v. Par. Pharm., Inc.*, No. 09-305, D.I. 5 (D.Del. May 19, 2009); and *Par Pharma, Inc. v. Novartis Pharma Corp.*, No. 14-843, D.I. 1 (D.Del. June 27, 2014).

FIRST CLAIM FOR RELIEF: '667 PATENT

18. Tris realleges paragraphs 1-17 above as if set forth specifically here.

19. The '667 patent, (copy attached as Exhibit A), entitled "Modified Release Formulations Containing Drug-Ion Exchange Resin Complexes," was issued on November 22, 2011 to Tris, upon assignment from the inventors Ketan Mehta and Yu-Hsing Tu. The '667 patent claims, *inter alia,* aqueous pharmaceutical suspensions for oral ingestion.

20. Plaintiff Tris has been and still is the owner of the '667 patent. The '667 patent will expire on March 29, 2029.

21. In the December 22 Notice Letter, Par Inc. notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '667 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '667 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

22. On information and belief, at the time the December 22 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 21 above.

23. Defendants acknowledged and represented that the December 22 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 21, above.

24. The December 22 Notice Letter alleges that Par's ANDA Product does not infringe claims 7, 11, 12, 29-31 and 33-40 of the '667 Patent. Par alleges that it does not infringe claims 7, 11 and 12 of the '667 Patent because Par's ANDA Product "will not contain any drug in addition to methylphenidate, and will not contain an antihistamine." Par also alleges that it

does not infringe claims 37-40 of the '667 patent because Par's ANDA Product "will not contain dextromethorphan." Par also alleges that it does not infringe claim 29-31 and 33-36 of the '667 patent because Par's ANDA Product "will not contain the drugs required by these claims [hydrocodone, clonidine, pseudoephedrine, carbinoxamine, diphenhydramine, ibuprofen, and morphine]."

25. The December 22 Notice Letter provides no other explanation or allegation why Par's ANDA Product does not infringe any claim of the '667 patent.

26. Par failed to address non-infringement of claims 1-6, 8-10, 13-28, 32 and 41-55 of the '667 patent as required by statute and regulation (see paragraph 21, above), thus acknowledging that its ANDA Product meets the all the limitations of these claims.

27. Par infringed one or more of the '667 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '667 patent.

28. Unless enjoined by this Court, Par will directly infringe the '667 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Par's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

29. Unless enjoined by this Court, Par will induce the infringement of the '667 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Par's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '667 patent and in violation of 35 U.S.C. § 271(b).

30. Unless enjoined by this Court, Par will induce the infringement of the ’667 patent by actively and intentionally encouraging, through its label, the infringing use of Par’s ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris’s rights under the ’667 patent and in violation of 35 U.S.C. § 271(b).

31. Unless enjoined by this Court, Par will contribute to the infringement of the ’667 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Par’s ANDA Product or equipment for the manufacture of Par’s ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Par’s ANDA Product in contravention of Tris’s rights under the ’667 patent in violation of 35 U.S.C. § 271(c).

32. Tris will be substantially and irreparably damaged and harmed if Par’s infringement of the ’667 patent is not enjoined.

33. Tris does not have an adequate remedy at law for Par’s infringement of the ’667 patent.

34. In the December 22 Notice Letter, Par has presented no reasonable or good faith position that the ’667 patent claims are invalid.

35. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney’s fees under 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF: ’903 PATENT

36. Tris realleges paragraphs 1-35 above as if set forth specifically here.

37. The ’903 patent, (copy attached as Exhibit B), entitled “Orally Effective Methylphenidate Extended Release Powder And Aqueous Suspension Product,” was issued on October 16, 2012 to Tris, upon assignment from the inventors Ketan Mehta, Yu-Hsing Tu and Ashok Perumal. The ’903 patent claims, *inter alia*, a methylphenidate aqueous extended release oral suspension and powder blend.

38. Plaintiff Tris has been and still is the owner of the ’903 patent. The ’903 patent will expire on February 15, 2031.

39. In the December 22 Notice Letter, Par Inc. notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the ’903 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the ’903 patent, “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .” 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to “include a detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include “[a] detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.”

40. On information and belief, at the time the December 22 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 39 above.

41. Defendants acknowledged and represented that the December 22 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 39, above.

42. The December 22 Notice Letter provides no explanation or allegation why Par's ANDA Product does not infringe any claim of the '903 patent.

43. By failing to address non-infringement of any claims of the '903 patent, Par acknowledged that its ANDA Product meets the all the limitations of these claims.

44. Par infringed the '903 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '903 patent.

45. Unless enjoined by this Court, Par will directly infringe the '903 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Par's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

46. Unless enjoined by this Court, Par will induce the infringement of the '903 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Par's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '903 patent and in violation of 35 U.S.C. § 271(b).

47. Unless enjoined by this Court, Par will induce the infringement of the '903 patent by actively and intentionally encouraging, through its label, the infringing use of Par's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris's rights under the '903 patent and in violation of 35 U.S.C. § 271(b).

48. Unless enjoined by this Court, Par will contribute to the infringement of the '903 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Par's ANDA Product or equipment for the manufacture of Par's ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Par's ANDA Product in contravention of Tris's rights under the '903 patent in violation of 35 U.S.C. § 271(c).

49. Tris will be substantially and irreparably damaged and harmed if Par's infringement of the '903 patent is not enjoined.

50. Tris does not have an adequate remedy at law for Par's infringement of the '903 patent.

51. In the December 22 Notice Letter, Par has presented no reasonable or good faith position that the '903 patent claims are invalid.

52. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF: '765 PATENT

53. Tris realleges paragraphs 1-52 above as if set forth specifically here.

54. The '765 patent, (copy attached as Exhibit C), entitled "Orally Effective Methylphenidate Extended Release Powder And Aqueous Suspension Product," was issued on June 18, 2013 to Tris, upon assignment from the inventors Ketan Mehta, Yu-Hsing Tu and Ashok Perumal. The '765 patent claims, *inter alia*, a methylphenidate aqueous extended release oral suspension, and methods of treatment of a patient with such a suspension.

55. Plaintiff Tris has been and still is the owner of the '765 patent. The '765 patent will expire on February 15, 2031.

56. In the December 22 Notice Letter, Par Inc. notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '765 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '765 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

57. On information and belief, at the time the December 22 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 56 above.

58. Defendants acknowledged and represented that the December 22 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 56, above.

59. The December 22 Notice Letter provides no explanation or allegation why Par's ANDA Product does not infringe any claim of the '765 patent.

60. By failing to address non-infringement of any claims of the '765 patent, Par acknowledged that its ANDA Product meets the all the limitations of these claims.

61. Par infringed the '765 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '765 patent.

62. Unless enjoined by this Court, Par will directly infringe the '765 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Par's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

63. Unless enjoined by this Court, Par will induce the infringement of the '765 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Par's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '765 patent and in violation of 35 U.S.C. § 271(b).

64. Unless enjoined by this Court, Par will induce the infringement of the ’765 patent by actively and intentionally encouraging, through its label, the infringing use of Par’s ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris’s rights under the ’765 patent and in violation of 35 U.S.C. § 271(b).

65. Unless enjoined by this Court, Par will contribute to the infringement of the ’765 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Par’s ANDA Product or equipment for the manufacture of Par’s ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Par’s ANDA Product in contravention of Tris’s rights under the ’765 patent in violation of 35 U.S.C. § 271(c).

66. Tris will be substantially and irreparably damaged and harmed if Par’s infringement of the ’765 patent is not enjoined.

67. Tris does not have an adequate remedy at law for Par’s infringement of the ’765 patent.

68. In the December 22 Notice Letter, Par has presented no reasonable or good faith position that the ’765 patent claims are invalid.

69. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney’s fees under 35 U.S.C. § 285.

FOURTH CLAIM FOR RELIEF: ’033 PATENT

70. Tris realleges paragraphs 1-69 above as if set forth specifically here.

71. The ’033 patent, (copy attached as Exhibit D), entitled “Orally Effective Methylphenidate Extended Release Powder And Aqueous Suspension Product,” was issued on October 22, 2013 to Tris, upon assignment from the inventors Ketan Mehta, Yu-Hsing Tu and Ashok Perumal. The ’033 patent claims, *inter alia*, a methylphenidate aqueous extended release oral suspension, and methods of treatment of a patient with such a suspension.

72. Plaintiff Tris has been and still is the owner of the ’033 patent. The ’033 patent will expire on February 15, 2031.

73. In the December 22 Notice Letter, Par Inc. notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the ’033 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the ’033 patent, “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .” 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to “include a detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include “[a] detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.”

74. On information and belief, at the time the December 22 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 73 above.

75. Defendants acknowledged and represented that the December 22 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 73, above.

76. The December 22 Notice Letter provides no explanation or allegation why Par's ANDA Product does not infringe any claim of the '033 patent.

77. By failing to address non-infringement of any claims of the '033 patent, Par acknowledged that its ANDA Product meets the all the limitations of these claims.

78. Par infringed the '033 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '033 patent.

79. Unless enjoined by this Court, Par will directly infringe the '033 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Par's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

80. Unless enjoined by this Court, Par will induce the infringement of the '033 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Par's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '033 patent and in violation of 35 U.S.C. § 271(b).

81. Unless enjoined by this Court, Par will induce the infringement of the ’033 patent by actively and intentionally encouraging, through its label, the infringing use of Par’s ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris’s rights under the ’033 patent and in violation of 35 U.S.C. § 271(b).

82. Unless enjoined by this Court, Par will contribute to the infringement of the ’033 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Par’s ANDA Product or equipment for the manufacture of Par’s ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Par’s ANDA Product in contravention of Tris’s rights under the ’033 patent in violation of 35 U.S.C. § 271(c).

83. Tris will be substantially and irreparably damaged and harmed if Par’s infringement of the ’033 patent is not enjoined.

84. Tris does not have an adequate remedy at law for Par’s infringement of the ’033 patent.

85. In the December 22 Notice letter, Par has presented no reasonable or good faith position that the ’033 patent claims are invalid.

86. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney’s fees under 35 U.S.C. § 285.

FIFTH CLAIM FOR RELIEF: ’390 PATENT

87. Tris realleges paragraphs 1-86 above as if set forth specifically here.

88. The ‘390 patent, (copy attached as Exhibit E), entitled “Orally Effective Methylphenidate Extended Release Powder And Aqueous Suspension Product,” was issued on July 15, 2014 to Tris, upon assignment from the inventors Ketan Mehta, Yu-Hsing Tu and Ashok Perumal. The ’390 patent claims, *inter alia*, a methylphenidate aqueous extended release oral suspension, and methods of treatment of a patient with such a suspension.

89. Plaintiff Tris has been and still is the owner of the ’390 patent. The ’390 patent will expire on February 15, 2031.

90. In the December 22 Notice Letter, Par Inc. notified Tris that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the ’390 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the ’390 patent, “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .” 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to “include a detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include “[a] detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.”

91. On information and belief, at the time the December 22 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 90 above.

92. Defendants acknowledged and represented that the December 22 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 90, above.

93. The December 22 Notice Letter provides no explanation or allegation why Par's ANDA Product does not infringe any claim of the '390 patent.

94. By failing to address non-infringement of any claims of the '390 patent, Par acknowledged that its ANDA Product meets the all the limitations of these claims.

95. Par infringed the '390 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '390 patent.

96. Unless enjoined by this Court, Par will directly infringe the '390 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Par's ANDA Product in the United States in violation of 35 U.S.C. §§ 271(a).

97. Unless enjoined by this Court, Par will induce the infringement of the '390 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Par's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Tris's rights under the '390 patent and in violation of 35 U.S.C. § 271(b).

98. Unless enjoined by this Court, Par will induce the infringement of the ’390 patent by actively and intentionally encouraging, through its label, the infringing use of Par’s ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Tris’s rights under the ’390 patent and in violation of 35 U.S.C. § 271(b).

99. Unless enjoined by this Court, Par will contribute to the infringement of the ’390 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Par’s ANDA Product or equipment for the manufacture of Par’s ANDA Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Par’s ANDA Product in contravention of Tris’s rights under the ’390 patent in violation of 35 U.S.C. § 271(c).

100. Tris will be substantially and irreparably damaged and harmed if Par’s infringement of the ’390 patent is not enjoined.

101. Tris does not have an adequate remedy at law for Par’s infringement of the ’390 patent.

102. In the December 22 Notice Letter, Par has presented no reasonable or good faith position that the ’390 patent claims are invalid.

103. This case is an exceptional one, and Tris is entitled to an award of reasonable attorney’s fees under 35 U.S.C. § 285.

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment be entered that Par has infringed the ’667 patent, the ’903 patent, ’765 patent, the ’033 patent, and the ’390 patent by submitting ANDA 206926 to the FDA;

(b) A judgment be entered declaring that the effective date of any approval of Par’s ANDA 206926 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug product “Methylphenidate HCl Extended Release Oral Suspension, CII” must be later than the expiration date of the patents in suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(c) A declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Par’s ANDA Product will directly infringe, induce and/or contribute to infringement of the ’667 patent, the ’903 patent, ’765 patent, the ’033 patent, and the ’390 patent;

(d) Preliminary and permanent injunctions be granted enjoining Par and its officers, agents, attorneys, and employees, and those acting in privity or concert with them from making, using, selling, offering to sell, or importing Par’s ANDA Product until after the expiration of the ’667 patent, the ’903 patent, ’765 patent, the ’033 patent, the ’390 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(e) A permanent injunction be granted pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Par, its officers, agents, attorneys, and employees, and those acting in privity or concert with them from practicing any composition or method claimed in the ’667 patent, the ’903 patent, ’765 patent, the ’033 patent, or the ’390 patent, or from actively inducing or contributing to the infringement of the ’667 patent, the ’903 patent, ’765 patent, the ’033 patent, and the ’390 patent, until after the expiration of, respectively, the ’667 patent, the ’903

patent, ’765 patent, the ’033 patent, and the ’390 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(f) An award of damages be granted if Par engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Par’s ANDA Product prior to the expiration of the ’667 patent, the ’903 patent, ’765 patent, the ’033 patent, or the ’390 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(g) A judgment be entered declaring that the ’667 patent, the ’903 patent, ’765 patent, the ’033 patent, and the ’390 patent remain valid, remain enforceable and have been infringed by Par;

(h) A judgment be entered that Par’s defenses and claims for relief with respect to the ’667 patent, the ’903 patent, ’765 patent, the ’033 patent and the ’390 patent are limited to those presented in the December 22 Notice Letter;

(i) A judgment be entered that Par’s conduct is exceptional;

(j) An award of attorneys’ fees be granted pursuant to 35 U.S.C. § 285;

(k) An award of costs and expenses be granted in this action; and

(l) Such other relief as this Court may deem proper.

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